K982078 IMMULITE RUBELLA QUANTITATIVE IGG, CATALOG # LKRBQ1 (100 TESTS), LKRBQ5 (500 TESTS)

CLEARED

Dec 11, 1998
179 days to decision

K982078 · Product code: **LFX** · Microbiology
Source: https://www.510kdatabase.net/k982078/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Jun 15, 1998
Decision date	Dec 11, 1998
Days to decision	179 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Diagnostic Products Corp.**
Location	Mchenry, IL, US
Contact	EDWARD M LEVINE
510(k) history	321 submissions · 321 cleared · 1976-2006